Over-The-Counter Topical Acne Products: Drug Safety Communication - Rare But Serious Hypersensitivity Reactions

Sold under various brand names such as Proactiv, Neutrogena, MaxClarity, Oxy, Ambi, Aveeno, Clean & Clear, and as store brands.

[Posted 06/25/2014]

AUDIENCE: Consumer, Pharmacy, Family Practice

ISSUE: FDA is warning that certain over-the-counter (OTC) topical acne products can cause rare but serious and potentially life-threatening allergic reactions or severe irritation. Consumers should stop using their topical acne product and seek emergency medical attention immediately if they experience hypersensitivity reactions such as throat tightness; difficulty breathing; feeling faint; or swelling of the eyes, face, lips, or tongue. Consumers should also stop using the product if they develop hives or itching. The hypersensitivity reactions may occur within minutes to a day or longer after product use.

These serious hypersensitivity reactions differ from the local skin irritation that may occur at the product application site, such as redness, burning, dryness, itching, peeling, or slight swelling, that are already included in the Drug Facts labels.

The hypersensitivity reactions may occur within minutes to a day or longer after product use. The OTC topical acne products of concern are marketed under various brand names such as Proactiv, Neutrogena, MaxClarity, Oxy, Ambi, Aveeno, Clean & Clear, and as store brands. They are available as gels, lotions, face washes, solutions, cleansing pads, toners, face scrubs, and other
products.

**BACKGROUND:** Based on the information reported to FDA, it cannot be determined if the serious hypersensitivity reactions were triggered by the acne products’ active ingredients, benzoyl peroxide or salicylic acid, the inactive ingredients, or by a combination of both. FDA is continuing to monitor and evaluate this safety issue, and will work with manufacturers regarding any future label changes that would address the risk of severe hypersensitivity reactions.

**RECOMMENDATION:** Before using an OTC topical acne drug product for the first time, apply a small amount to one or two small affected areas for 3 days to make sure you don’t develop any hypersensitivity symptoms. If no discomfort occurs, follow the directions on the Drug Facts label.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Download form ([/Safety/MedWatch/HowToReport/DownloadForms/default.htm](/Safety/MedWatch/HowToReport/DownloadForms/default.htm)) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[06/25/2014 - Consumer Update ([ForConsumers/ConsumerUpdates/ucm402441.htm](/ForConsumers/ConsumerUpdates/ucm402441.htm)) - FDA]